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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,492	03/04/2002	Timothy A.M. Chuter	ENDOV-55673	5068

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EXAMINER

THALER, MICHAEL H

ART UNIT PAPER NUMBER

3731

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/090,492

Applicant(s)

CHUTER ET AL.

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-13, 15, 29-46, 48, 49, 56, 61, 62, 70, 72-79 and 87-93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-13, 15, 29-46, 48, 49, 56, 61, 62, 70, 72-79 and 87-93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 9-13, 15, 29-46, 48, 49, 56, 61, 62, 70, 72-79 and 87-93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 is confusing and inaccurate. Specifically, the text in line 10 that indicates that the expandable frame is longitudinally separated from the graft component is confusing and inaccurate. According to the specification, the expandable frame includes the elongated struts (unlabeled) and the connector eyelets 41 at the distal end of the elongated struts (page 19, line 12 and page 25, lines 1-4). Thus, the expandable frame (which includes the elongated struts and the connector eyelets 41) is not longitudinally separated from tabs 47 of the graft component. It appears that only the upper portion of expandable frame 40 (as seen in figure 1P) is longitudinally separated from tabs 47 of the graft component by the lower portion of the expandable frame (which includes the elongated struts and eyelets 41). In addition, the phrase in claim 9, lines 13-14 after the word "wherein" is simply not understood. First, the opening is open space and therefore by definition lacks structure. Even if the opening is meant to be the graft material surrounding and defining the opening, then this "opening" in fact includes structure which

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forms the remainder of the opening circumference. Further, it is not seen what structure could support an opening circumference. Claim 72 is indefinite for the same reasons. As to claim 62, it is not understood where the endpoints that are larger than a strut thickness are in the elected species.

Claims 9-13, 15, 29-33, 35-40, 42, 56, 61, 62, 70, 72, 88-90, 92 and 93 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kugler et al. (6,280,466). Kugler et al., in figures 3B and 6A, disclose graft component 45 having an opening and a plurality of structures (the triangular tabs at the top of the graft component 45 as seen in figure 3B and described in col. 15, lines 32-34) extending longitudinally beyond the opening (which is located at the base of the triangular tabs), expandable frame 50 (described in col. 10, lines 7-9, which is independently expandable from the caudal zone as indicated in col. 8, lines 46-48 and col. 9, lines 51-54 and thus, by itself, may be considered a "frame"), attaching structure 55, anchoring structure (the barbs 58 which can be placed at the cranial end 50 as indicated in col. 11, lines 61-63), wherein the expandable frame 50 is longitudinally separated from the graft component 45 (by members 55), wherein the attaching structure 55 attaches the expandable frame to the graft component at discrete locations on

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the graft component (i.e. at the apexes of the triangular tabs) so that less than an entirety of a graft circumference is affixed to the attaching structure 55. As to the indefinite limitation in claim 9, lines 13-14, as best understood, the opening located at the base of the triangular tabs of Kugler et al. does not include any additional structure and therefor meets this unclear limitation. Alternatively, it would have been obvious that member 50, by itself, is a "frame" for the reasons set forth above. As to claims 12 and 13, the edge portions of each tab would inherently be wrapped partially around the struts 53a, b, c, d when sutures (at 25) are wrapped around the struts and bite into the graft material as described in col. 15, line 37 to col. 16, line 4, resulting in a folding of each tab to some extent. As to claim 35, the end portion of barb 58 comprises a tail. As to claim 36, barb 58 is at the end of an edge of a strut. As to claims 38-40, Kugler et al. disclose reinforcing stent 30. As to claim 61, the endpoints of stent 30 at one end are longitudinally offset from the endpoints at the opposite end. As to claim 70, radiopaque markers 28a-28e are variable sized as seen in figure 3B, noting that some markers extend longitudinally to a greater extent than others. As to claim 72, Kugler et al. disclose first expandable frame 50 and second expandable frame 30. As to claim 88, the Kugler et al.

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reinforcing structures, expandable frame and anchoring structure are non-overlapping.

Claims 34, 43-46, 48, 49 and 73-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kugler et al. (6,280,466). As to claim 34, Kugler et al. fail to disclose the barb being bidirectional. However, it was well known in this art to make stent barbs bidirectional so that they are securely attached to the artery. It would have been obvious to make the Kugler et al. barbs 58 bidirectional so that it too would have this advantage. The above well known in the art statement is taken to be admitted prior art because applicant failed to traverse the examiner's assertion (M.P.E.P. 2144.03). As to claims 43 and 73, Kugler et al. fail to disclose the stent 30 as including a barb. However, Kugler et al. teach that stents (e.g. at 52) should include barbs so that they can be securely attached to the artery (col. 11, lines 58-63). It would have been obvious to include barbs on the Kugler et al. stent 30 so that this stent too would have this advantage. As to claims 89 and 93, the first leg portion is attached along its length to the second leg portion.

Claims 41, 87 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kugler et al. (6,280,466) in view of Dehdashtian et al. (6,368,345). As to claim 41, Kugler et al.

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fail to disclose the stent 30 being on the exterior of the graft component. However, Dehdashtian et al. teach that stents should be placed both on the exterior and interior of a graft apparently to properly support it (col. 11, line 55 to col. 12, line 4) It would have been obvious to so locate the stents on the Kugler et al. graft so that it too would have this advantage.

Applicant's arguments filed Feb. 22, 2005 have been fully considered but they are not persuasive. As to the rejection under 35 U.S.C. 112, second paragraph, according to the specification, the attaching structure (the unlabeled elongated struts and the connector eyelets 41 at the distal end of the elongated struts in figure 1P) is part of the expandable frame. Therefore, according to the specification, the expandable frame extends to the graft component. The claims are read in light of the specification and therefore must be consistent with the specification. However, the claims are inconsistent with the specification. According to the specification, the bottom of the expandable frame is at eyelets 41. According to the claim 9, the bottom of the expandable frame must be near the top of reference numeral 43 in figure 1P. As to claim 62, if the end points of the expandable frame which are larger than a strut thickness of the expandable frame are eyelets 41, then according

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to this claim, the expandable frame includes eyelets 41 and therefore the expandable frame is not longitudinally separated from the graft component.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the

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organization where this application or proceeding is assigned is
(703)872-9306.

mht

3/25/05

A handwritten signature in black ink, appearing to read 'Michael Thaler', written in a cursive style.

MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731